

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Wai et al.	
Patent No.: 7,517,532	Art Unit: 1624
Issue Date: April 14, 2009	
Serial No.: 10/526,275	Examiner:
Docket No.: 21162YP	Murray, Jeffrey H.
Filed: March 1, 2005	
For: DIHYDROXYPYRIDOPYRAZINE-1,6-DIONE COMPOUNDS USEFUL AS HIV INTEGRASE INHIBITORS	Confirmation No. 8334

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF APPLICATION FOR PATENT TERM
ADJUSTMENT UNDER 37 CFR 1.705(b)

Sir:

This is a request for reconsideration under 37 C.F.R. 181 of the USPTO decision dated December 15, 2009 ("Decision"; attached as Exhibit One) dismissing the application for patent term adjustment ("PTA Application") filed April 17, 2009 for US 7,517,532. The Decision was under the USPTO's pre-Wyeth interpretation of 35 U.S.C. 154(b)(2)(A). This request for consideration is being filed within two months of the date of the Decision and the sole basis for requesting reconsideration of the Decision is the USPTO's pre-Wyeth interpretation of 35 U.S.C. 154(b)(2)(A). It is believed that the patent is entitled to 630 days under 35 U.S.C. 154(b)(1)(A) plus 399 days pursuant to 35 U.S.C. 154(b)(1)(B) less 38 overlapping days = 991 days of PTA.

The PTA Application (attached as Exhibit Two excluding its attachments) is incorporated by reference herein. It is stated therein that there were 409 days of delay under 37 CFR 1.703(b). That value is incorrect. The correct value is 399 days, because, as set forth in the paragraph bridging pages 1 and 2 of the Decision, the patent issued 3 years and 399 days (not 409 days) after the national stage commenced. The facts and statements in the PTA Application are otherwise believed to be correct. Incorporating this correction into the PTA Application, the PTA is 991 days.

Form PTO/SB/131 is enclosed herewith.

It is requested that the PTA determination for US 7,517,532 be changed to 991 days.

No fee is believed to be due as a result of the submission of this request. However, if a fee is due, the Commissioner is authorized to charge the fee to Deposit Account No. 13-2755.

Respectfully submitted,
By: /Kenneth R. Walton, Reg. No. 32,951/
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Date: February 3, 2010

Enclosure (PTO/SB/131)
Attachments (Exhibits 1 & 2)

Exhibit 1

Doc Code: PET.PTA.RCAL

Document Description: Request for Recalculation in view of Wyeth

PTO/SB/131 (01-10)
Approved for use through 02/28/2011, OMB 0651-0020

U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE

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REQUEST FOR RECALCULATION OF PATENT TERM ADJUSTMENT
IN VIEW OF *WYETH**

Attorney Docket Number: 21162YP	Patent Number: 7,517,532
Filing Date (or 371(b) or (f) Date): March 11, 2008	Issue Date: April 14, 2009
First Named Inventor: John S. Wai	
Title: Dihydropyridopyrazine-1,6-dione Compounds Useful as HIV Integrase Inhibitors	

PATENTEE HEREBY REQUESTS RECALCULATION OF THE PATENT TERM ADJUSTMENT (PTA) UNDER 35 USC 154(b) INDICATED ON THE ABOVE-IDENTIFIED PATENT. THE PATENTEE'S SOLE BASIS FOR REQUESTING THE RECALCULATION IS THE USPTO'S PRE-*WYETH* INTERPRETATION OF 35 U.S.C. 154(b)(2)(A).

Note: This form is only for requesting a recalculation of PTA for patents issued before March 2, 2010, if the sole basis for requesting the recalculation is the USPTO's pre-*Wyeth* interpretation of 35 U.S.C. 154(b)(2)(A). See Instruction Sheet on page 2 for more information.

Patentees are reminded that to preserve the right to review in the United States District Court for the District of Columbia of the USPTO's patent term adjustment determination, a patentee must ensure that he or she also takes the steps required under 35 U.S.C. 154(b)(3) and (b)(4) and 37 CFR 1.705 in a timely manner.

**Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir., Jan. 7, 2010).

Signature /Kenneth R. Walton, Reg. No. 32,951/	Date February 3, 2010
Name (Print/Typed) Kenneth R. Walton	Registration Number 32,951
<p>Note: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below*.</p>	
<p><input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>	

The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



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DEC 15 2009

In re Patent No. 7,517,532
Issued: April 14, 2009
Application No. 10/526,275
Filed: March 1, 2005
Dkt. No.: 21162YP

: OFFICE OF PETITIONS
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: PATENT TERM ADJUSTMENT
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This is a decision on the "APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(b)," filed April 17, 2009. Patentees request correction of the patent term adjustment from 630 days to 1,001 days. Patentees requested this correction on the sole basis that the Office took in excess of three years to issue the above-referenced patent. This matter is being properly treated under 37 CFR 1.705(d).

The application for patent term adjustment (PTA) under 37 CFR 1.705(d) is **DISMISSED**.

The above-identified application matured into U.S. Pat. No. 7,517,532 on April 14, 2009. The patent issued with a patent term adjustment of 630 days. The instant application for patent term adjustment was timely filed in accordance with 37 CFR 1.705(d). Applicants argued that in view of *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008), the patent was entitled to an adjustment of 1,001 days (630 days pursuant to 35 USC 154(b)(1)(A) *plus* 409 days pursuant to 35 USC 154(b)(1)(B) *less* 38 overlapping days).

Patentees determined that the commencement date of the application is March 1, 2008 and, thus, calculate a period of over three year delay of 409 days (March 1, 2008 to April 14, 2009). This calculation, however, is not accurate, as discussed herein.

Under 37 CFR 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR 1.702 reduced by the period of time equal to the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. In other words, patentees are entitled to the period of Office delay reduced by the period of applicant delay.

The Office asserts that as of the issuance of the patent on April 14, 2009, the application was pending three years and 399 days after the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application. The commencement date is the date 30 months from the earliest priority date claimed in the international application. In this application, the earliest priority date claimed, as shown on the Notice of Acceptance of Application Under 35 U.S.C. § 371 and 37 CFR 1.495, mailed September 30, 2005, is September 11, 2002. Accordingly, the commencement date is March 11, 2005, and the period of adjustment pursuant to 37 CFR 1.703(b) began March 12, 2008, the day after the date that is three years after the date that

national stage commenced, and ended April 14, 2009, the date that the patent issued, or 399 days.

The Office asserts that certain action was not taken within the specified time frame, and thus, the adjustment of 630 days pursuant to 37 CFR 1.702(a) is correct. At issue is whether patentees should accrue 399 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as 630 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that the period of 399 days of delay in issuance of the patent under 37 CFR 1.702(b) overlaps with the period of 630 days of examination delay under 37 CFR 1.702(a). Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

To the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in *Explanation of 37 CFR 1.703(f)*¹ and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 54366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term*

¹ Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004).

Further, as stated in the *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after national stage commenced, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding §1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A) is the period during which the application was pending before the Office beginning on the date that national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, March 11, 2005, and ending on the date that the patent issued, April 14, 2009.

Pursuant to 35 U.S.C. 154(b)(1)(A) and 37 CFR 1.702(a), 630 days of examination delay accrued prior to issuance of patent. Pursuant to 35 U.S.C. 154(b)(1)(B) and 37 CFR 1.702(b), the application was pending three years and 399 days prior to the issuance of the patent on April 14, 2009.

The 399 days of delay in issuance of the patent under 37 CFR 1.702(b) overlap with the 630 days of patent term adjustment under 37 CFR 1.702(a). Entry of both the 399 days and the 630 days is neither permitted nor warranted given that 630 days is the actual number of days issuance of the patent was delayed.

Accordingly, at issuance, having considered the 399 days of Office delay under the three-year pendency provision in conjunction with the 630 days of examination delay, the Office properly entered 630 days of patent term adjustment.

In view thereof, no adjustment to the patent term will be made.

No additional fee is due in connection with this matter.

Telephone inquiries specific to this matter should be directed to the undersigned at (571) 272-3205.

A handwritten signature in black ink, appearing to read 'Alesia M. Brown', written in a cursive style.

Alesia M. Brown
Petitions Attorney
Office of Petitions